

Attachment B

Westlaw.

2002 WL 32334598 (Bd.Pat.App & Interf.)
(Cite as: 2002 WL 32334598 (Bd.Pat.App & Interf.))

*1 THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

Board of Patent Appeals and Interferences

Patent and Trademark Office (P.T.O.)

EX PARTE PETER MEISEL, KARL-FRIEDRICH LANDGRAF, JURGEN SCHAFER, WILFRIED THIEL,
MATTHIAS RISCHER, ALFRED OLBRICH, AND BERNHARD KUTSCHER

Appeal No. 2002-0438

Application No. 09/181,671

Heard: October 10, 2002

VENABLE, BAETJER, HOWARD & CIVILETTI, LLP

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WASHINGTON, DC 20005-3917

Before WINTERS, SCHEINER, and GREEN

Administrative Patent Judges

GREEN

Administrative Patent Judge

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-3 and 16. Claim 1 is drawn to Modification A of the compound 2-amino-4-(4-fluorobenzylamino)-1-ethoxy-carbonylaminobenzene, wherein the modification is "characterized by the X-ray diffractogram, reflections not coinciding with the reflections of the other two modifications being observed, inter alia, at $6.97^{\circ} 2\langle\text{THETA}\rangle$ (12.67 \AA), $18.02^{\circ} 2\langle\text{THETA}\rangle$ (4.92 \AA) and $19.94^{\circ} 2\langle\text{THETA}\rangle$ (4.45 \AA).". Claims 2 and 3 are drawn to Modification B and Modification C of the 2-amino-4-(4-fluorobenzylamino)-1-ethoxy-carbonylaminobenzene compound, each modification being defined by peaks appearing on the X-ray diffractogram. Claim 16 is drawn to pharmaceuticals "comprising the modification A, B or C" of the compound, "and, if appropriate, excipients and or auxiliaries." [FN1]

The examiner relies upon the following art:

German Patent Application

Dieter et al. (Dieter) DE 42 00 259 Jul. 15, 1993

Kirk-Othmer, "Crystallization," Encyclopedia of Chemical Technology, 4th Ed., Vol. 7, pp.700-702 (1993)

The claims stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Dieter and Kirk-Othmer. After careful consideration of the record and the issue before us, we reverse.

DISCUSSION

The Examiner's Answer rejects claims 1-3 and 16 as being obvious over the combination of Dieter and Kirk-Othmer. Dieter is cited for teaching the compound 2-amino-4-(4-fluorobenzylamino)-1-ethoxy-carbonylaminobenzene, as well as its use in

pharmaceutical compositions. Dieter does not discuss any possible crystal polymorphism of the disclosed compound.

Kirk-Othmer is cited for teaching that polymorphism is a condition in which a specific chemical compound may crystallize in different forms, that is, different space groups and with different physical and physico-chemical properties. An example is given of a simple compound, ammonium nitrate, with four form changes. In the paragraph which follows, it is stated that a specific **polymorph** may be absolutely essential for a particular crystalline product. By way of example, it is generally stated that one **polymorph** may have more desirable physico-chemical properties, i.e., color, hardness, solubility or stability than another.

*2 Examiner's Answer, page 3.

The examiner notes that the instant claims are distinguishable over the prior art on the basis that it crystallized in three distinct crystalline forms, but states that "this does not render the compound in these crystalline forms patentable over the compound itself. The compound is neither new or novel, nor is its claimed use." Id. at 4. The rejection concludes that:

It would have been obvious to one of ordinary skill in the art at the time of the invention that the three crystalline forms claimed by appellant[s] were intrinsic to the compound of the prior art, motivated by the fact that it is well known in the chemical arts that crystal polymorphism is a common and commonly recognized property of crystalline compounds.

Id.

Appellants argue that the examiner has failed to set forth a prima facie case of obviousness. Specifically, appellants argue that, at best, the combination teaches that the claimed compound may have polymorphisms that may be separable, thus the rejection fails to provide a reasonable expectation of success in arriving at the claimed invention. See Appeal Brief, page 6. We agree.

The burden is on the examiner to make a prima facie case of obviousness, and the examiner may meet this burden by demonstrating that the prior art would lead the ordinary artisan to combine the relevant teachings of the references to arrive at the claimed invention. See In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598-99 (Fed. Cir. 1988). The findings of fact underlying the obviousness rejection, as well as the conclusions of law, must be made in accordance with the Administrative Procedure Act, 5 U.S.C. § 706 (A), (E) (1994). See Zurko v. Dickinson, 527 U.S. 150, 158, 119 S.Ct. 1816, 1821, 50 USPQ2d 1930, 1934 (1999). Findings of fact underlying the obviousness rejection, upon review by the Court of Appeals for the Federal Circuit, must be supported by substantial evidence within the record. See In re Gartside, 203 F.3d 1305, 1315, 53 USPQ2d 1769, 1775 (Fed. Cir. 2000). In addition, in order for meaningful appellate review to occur, the examiner must present a full and reasoned explanation of the rejection. See, e.g., In re Lee, 277 F.3d 1338, 1342, 61 USPQ2d 1430, 1432 (Fed. Cir. 2002).

The rejection of record does not meet the above criteria. Dieter, while teaching the compound that is the subject of the claims is known, does not teach or suggest that the compound has different crystalline structures. Thus, the rejection of record does not set forth any motivation to combine Dieter with Kirk-Othmer because, although Kirk-Othmer does teach that it is known that crystal polymorphism is known generally to exist, there is no teaching or suggestion in the references that the compound of the claimed invention is known to exhibit such polymorphism.

*3 Moreover, the record demonstrates that the compound as prepared by the prior art is a mixture of crystal **polymorphs**, whereas appellants have succeeded in isolating three distinct **polymorphs**, i.e., Modifications A, B and C. See Declaration of Wilfried Thiel, Paper No. 9. Thus, the isolated crystal **polymorphs** as claimed in the instant application do not appear to be an inherent property of the claimed compound as disclosed by the prior art of record.

CONCLUSION

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Because the rejection of record does not set forth a prima facie case of obviousness, it is reversed.

REVERSED

BOARD OF PATENT APPEALS AND INTERFERENCES

Sherman D. Winters

Administrative Patent Judge

Toni R. Scheiner

Administrative Patent Judge

Lora M. Green

Administrative Patent Judge

FN1. Note that the panel is interpreting this claim as requiring one of Modification A, Modification B or Modification C, but excluding mixtures of the disclosed modifications.

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